

REMARKS

A. Status of the Claims

Currently, claims 1, 9-10, 12-13, and 15-25 are pending, with claims 24 and 25 being withdrawn. The claims presented for examination are claims 1, 9-10, 12-13, and 15-23.

Claim 21 is rejected under 35 U.S.C. §112, ¶2, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicant regards as the invention.

Claims 1, 9-10, 12-13, and 15-23 are rejected under 35 U.S.C. §112, ¶1, for allegedly failing to meet the written description requirement.

Claims 1, 9-10, 12-13, and 15-23 are rejected under 35 U.S.C. §101 for allegedly being directed to non-statutory subject matter.

Claims 1, 9-10, 12-13, and 15-23 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by International Application No. WO 01/58934 to Albericio et al. (“Albericio”).

Claims 1, 9-10, 12-13, and 15-23 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by a Ph.D. thesis by Angel Lopez Macia (“Lopez Macia”).

B. Explanation of the Claim Amendments

In this response, claim 21 has been amended to delete “(4RS)-MeHex.”

In addition, all of the pending claims (i.e., claims 1, 9-10, 12-13, and 15-25) have been amended to recite “an analogue of kahalalide F.” Support for this amendment generally found through the specification. See, e.g., original specification at page 4, lines 6-7. Applicants respectfully assert that no new matter has been added by these amendments.

C. Status of the Specification

The Office Action objects to the originally filed specification for lacking page numbers, as well as for the use of commas, rather than periods, in the decimal numbers found in the tables on pages 62-80. Office Action at 3-4. In response, Applicants have submitted with this paper a Substitute Specification having numbered pages and corrected tables. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of objection.

D. Rejection under 35 U.S.C. §112, ¶2

The Office Action asserts that claim 21 is indefinite under 35 U.S.C. § 112, ¶2. In view of Applicants' amendments to claim 21, Applicants respectfully submit that the rejection is moot and respectfully request reconsideration and withdrawal of the rejection.

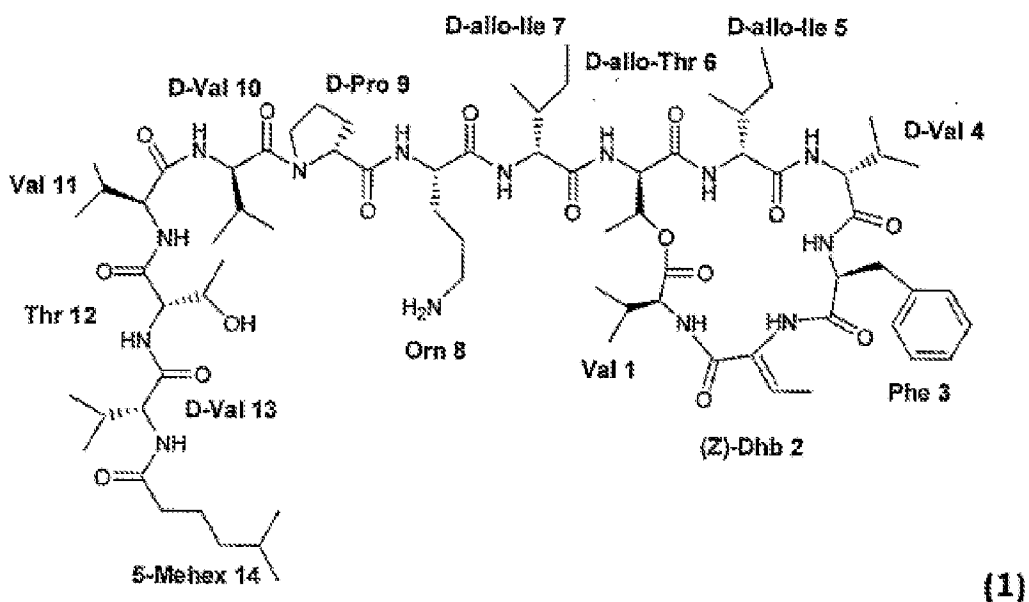
E. Rejections under 35 U.S.C. §112, ¶1

The Office Action asserts that claims 1, 9-10, 12-13, and 15-23 fail to meet the written description requirement of under 35 U.S.C. § 112, ¶1. Office Action at 6-13. Applicants respectfully traverse.

The Office Action's rejection under 35 U.S.C. §112, ¶1 is based upon the claim term "compound" and the Examiner's understanding of this term based on a passage on page 19 in the originally filed specification. According to the Office Action, "[t]he instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of a compound." Office Action at 9. On this basis, the Office Action calculates that the size of the genus is at least 20¹⁰ compounds and that the species disclosed in Table VI of Applicants' specification only represent

“a small fraction of the possible variety of compounds in the genus.” *Id.* Thus, the Office Action concludes that “[o]ne of skill in the art would not recognize that applicant was in possession of the claimed genus.” Office Action at 10.

Applicants respectfully assert that the Office Action’s rejection is moot. The presently pending claims, as amended, no longer recite “a compound,” but rather “an analogue of kahalalide F.” Thus, the Office Action’s statements concerning the phrase “a compound” and the size of the associated genus are inapposite. Furthermore, the Office Action’s statement that claim 1 fails to specify a “significant structural core” is moot in view of Applicants’ amendment of claim 1. In particular, claim 1 specifies that the claimed analogue (or pharmaceutically acceptable salt thereof) has a core structure, that of kahalalide F,



except that the “L-Orn at position 8 is substituted by another natural or non natural amino acid, and/or is masked with one or more substituent organic groups” and that the “analogue may optionally differ from formula 1 by modification of the terminal acyl group.” *See* claim 1, as amended. In view of these amendments, as well as Applicants’ disclosure, which illustrates

several exemplary species within the claimed genus (*see, e.g.*, original specification at 7:7-24, 16:5, 17:10-12; 17:17-20; and Table III), Applicants respectfully submit that written description requirements of 35 U.S.C. §112, ¶1 are fully met by the presently pending claims.

F. Rejections under 35 U.S.C. §101

The Office Action rejects claims 1, 9-10, 12-13, and 15-23 for allegedly being directed to a product of nature, which is unpatentable subject matter under 35 U.S.C. §101. Office Action at 13-14. Applicants respectfully traverse.

Like the rejection under 35 U.S.C. §112, ¶1, the Office Action's rejection under 35 U.S.C. §101 rests on the Examiner's interpretation of the term "compound" as used in the previous version of the claims. According to the Office Action, "Kahalalide F as shown on page 2 of Albericio also meet the claim limitation of compound since the compound includes a residue, for example Phe (see position 3) of the compounds as claimed." Office Action at 13.

In view of the claim amendments presented herein, the Office Action's rejection is rendered moot. More specifically, nowhere does Albericio disclose the claimed "analogue[s] of kahalalide F" exist in nature as natural products. Indeed, there is no evidence in the record--or of which Applicants are aware--that the presently claimed analogues are natural products. Accordingly, Applicants maintain that the presently claimed "analogue[s] of kahalalide F" constitute statutorily patentable subject matter and respectfully request reconsideration and withdrawal of the rejection of claims 1, 9-10, 12-13, and 15-23 under 35 U.S.C. §101.

G. Rejections Under 35 U.S.C. § 102(b)

Applicants respectfully traverse the rejection of claims 1, 9-10, 12-13, and 15-23 for allegedly being anticipated under 35 U.S.C. §102(b) by Albericio or Lopez Macia. Briefly, neither reference discloses the presently claimed analogues or the claimed methods of using such analogues to treat cancer. Accordingly, these rejections under 35 U.S.C. §102(b) should be withdrawn. *See Verdegaaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (stating that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”)

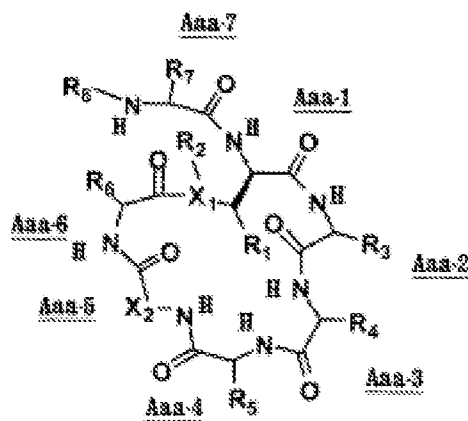
1. Albericio Does Not Anticipate Applicants’ Claims

As with the Office Action’s rejections under 35 U.S.C. §§101 and 112, ¶1, the rejection of the pending claims under 35 U.S.C. §102(b) for allegedly being anticipated by Albericio rests upon the Examiner’s understanding of the term “compound.” In particular, the Examiner contends that the term “compound” includes “pharmaceutical derivatives which are described as capable of providing a residue of the compound.” Office Action at 15. Under this reading of the term “compound,” the Examiner takes the position “compounds which include a residue of the compounds of the claims are also within the scope of the claims.” Office Action at 16. Thus, the Examiner contends that even kahalalide F, as shown on page 2 of Albericio, meets the limitations of Applicants’ claims, because kahalalide F contains Phe, which is found in the claimed compounds. *Id.*

Applicants respectfully traverse the rejection. As an initial matter, Applicants again note that the Office Action’s analysis with respect to the word “compound” has been rendered moot.

The presently pending claims no longer recite “a compound,” but instead are directed to “an analogue of kahalalide F.” *See, e.g.*, claim 1, as amended.

Moreover, Albericio fails to disclose the presently claimed analogues, as would be required to properly establish anticipation under 35 U.S.C. §102. At best, Albericio reports compounds related to kahalalide F, having the following general formula:



Formula II

Albericio at 5. More particularly, Albericio reports that Aaa-1, Aaa-2, Aaa-3, Aaa-4, Aaa-6 and Aaa-7 in Formula II are independently α -amino acids of L or D configuration. *Id.* In addition, Albericio states that R₁, R₂, R₃, R₄, R₅, R₆, and R₇ are each independently H or an organic group selected from a list of possible functional groups that spans pages 5-7 of Albericio. Albericio at 5-7.

As the Examiner will readily appreciate, Albericio’s description of Formula II embraces many compounds. As discussed in MPEP §2131.02, a compound is anticipated by a generic formula only if one is able to “at once envisage” the specific compound within the generic formula. *See* MPEP §2131.02, (citing to *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)). Furthermore, one of ordinary skill in the art must be able to draw the structural formula or write the name of *each of the compounds* included in the generic formula *before any of the*

compounds can be “at once envisaged.” *Id.* The Examiner has not shown that this is possible for the class of compounds embraced by Formula II of Albericio.

Accordingly, Applicants respectfully assert that none of the species in the presently claimed genus of “analogue[s] of kahalalide F” are disclosed in Albericio, and Albericio fails to anticipate claims 1, 9-10, 12-13, and 15-23. Applicants therefore respectfully request reconsideration and withdrawal of this ground of rejection

2. Lopez Macia Does Not Anticipate Applicants’ Claims

The Office Action rejects claims 1, 9-10, 12-13, and 15-23 under 35 U.S.C. § 102(b) for allegedly being anticipated by Lopez Macia. Office Action at pages 16-17. As with the Office Action’s rejection involving Albericio, the rejection over Lopez Macia rests on the Examiner’s understanding of the term “compound” as referring to “pharmaceutical derivatives which are described as capable of providing a residue of the compound.” *Id.* Based on this understanding, the Office Action takes the position that kahalalide F (shown on page 4 of Lopez Macia) and the compound 5-MeHex-Val-Thr(^tBu)-Val-Val-Pro-Orn(Boc)-Ile-Thr(Val-Fmoc)-Ile-Val-Cl-Trt-PS (shown in section 3.2.2.2 of Lopez Macia on page 7)) both anticipate the pending claims, because they contain a residue of the claimed compounds. *Id.* Applicants respectfully traverse.

Applicants again note that the Office Action’s analysis, which turns on the definition of the word “compound,” is now moot in view of Applicants’ amendments to the claims. The presently pending claims no longer recite “a compound,” but instead are directed to “an analogue of kahalalide F.” *See, e.g.*, claim 1, as amended.

Furthermore, Lopez Macia fails to anticipate the presently claimed invention, because it does not disclose the “analogue[s] of kahalalide F” required by the claims. In particular, neither

kahalalide F nor the compound 5-MeHex-Val-Thr(^tBu)-Val-Val-Pro-Orn(Boc)-Ile-Thr(Val-Fmoc)-Ile-Val-Cl-Trt-PS cited by the Examiner is an “an analogue of kahalalide F” as recited in Applicants’ pending claims. Moreover, no other passage in Lopez Macia discloses the presently claimed “analogue[s] of kahalalide F.”

Because Lopez Macia fails to disclose all of the features of the presently claimed invention, the rejection of Applicants’ claims under 35 U.S.C. §102 for allegedly being anticipated by Lopez Macia should be withdrawn. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

H. Non-statutory Obviousness Type Double Patenting

The Office Action maintains its rejections of claims 1, 9-10, 12-13, and 15-23 under the judicially created doctrine of non-statutory obviousness type double patenting in view of the following: (i) Claims 1-49 of U.S. Patent No. 7,482,429 (“the ‘429 Patent”); and (ii) claims 1-13 of co-pending U.S. Application Serial No. 11/587,177 (“the ‘177 Application”). Applicants respectfully traverse.

As with the rejections under 35 U.S.C. §§101, 102(b), and 112, ¶1, the Office Action’s obviousness-type double patenting rejections are based on the Examiner’s understanding of the word “compound.” For instance, with respect to the ‘429 Patent, the Office states the following:

compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by [the] ‘429 [Patent] such as 5-MeHex-D-Val-Thr-Val-D-Val-D-Pro-Orn-D-allo-Ile-cyclo(D-allo-Thr-D-allo-Ile-Val-Phe-Z-Dhb-Val)(claim 1) meet the limitation of being a compound since compound includes a residue, for example D-Val (see position 13), of the compounds as claimed.

Office Action at 19. Applicants respectfully submit that the Office Action's analysis is moot, because the presently pending claims do not recite the phrase "a compound," but instead call for "an analogue of kahalalide F." *See, e.g.,* claim 1, as amended. Applicants further submit that the claims of the '429 Patent concern subject matter that is patentably distinct from the presently claimed subject matter. For example, none of the claims in the '429 Patent cover the "analogue of kahalalide F" required by the present claims in this application. Furthermore, there is no teaching or suggestion in the '429 Patent to arrive at the presently claimed invention by modifying the compounds reported in or claimed by the '429 Patent. Accordingly, the obviousness-type double patent rejection over claims 1-49 of the '429 Patent should be withdrawn.

Similar arguments apply to the Office Action's obviousness-type double patenting rejection over the '177 Application. In particular, the Office Action contends that claim 3 of the '177 Application concerns subject matter that is not patentably distinct from the present claims. Office Action at 20. Again, however, the Office Action's reasoning turns on its definition of "compound," reasoning which is moot in view of the amendments presented herein. Furthermore, none of the claims in the '177 Patent cover the "analogue of kahalalide F" required by the present claims in this application. Additionally, there is no teaching or suggestion in the '177 Application to arrive at the presently claimed invention by modifying the compounds reported in the '177 Application. Accordingly, the obviousness-type double patent rejection over claims 1-13 of the '177 Application should be withdrawn.

CONCLUSION

Applicants respectfully request reconsideration of the rejections and objections presented in the Office Action, in view of the amendments and remarks presented herein. If a telephone call would help expedite prosecution of the instant application, Applicants encourage the Examiner to contact the undersigned representative of Applicants.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required for consideration of this paper to Deposit Account No. **50-3732**, Order No. 13566.105010. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 13566.105010.

Respectfully submitted,
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